

**REMARKS**

In the Office Action mailed July 24, 2008, Claims 1, 2, 13-15, 20-24, 29-33 and 38, 39, and 42-65 were pending for consideration. Claims 42 and 43 have been canceled while claims 44-65 remain withdrawn from consideration. All of the claims were objected to and/or rejected on various statutory grounds, each of which is addressed in turn below. By the present amendment, Claims 1, 32, and 33 have been amended to delete the inclusion of tocopherol polyethyleneglycol succinates from the lists of possible solubilizers and/or release solubilizers. Applicants submit that no new matter has been added in the by the above described amendments.

It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the correctness of the Examiner's rejection. Accordingly, Claims 1, 2, 13-15, 20-24, 29-33, and 38-39 remain pending. Applicants respectfully submit that the present claims are allowable over the cited references, and that the rejections in view thereof are now moot.

**35 U.S.C. § 102 Rejections:**

The Examiner has rejected Claims 1, 13-15, 20-24, 29, 32-33, 38, and 42-43 under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Pat. No. 5,891,469 (hereinafter "Amselem"). As discussed above, the presently pending claims have been amended to delete TPGS from the pending claims, specifically from the Markush Groups for both solubilizers and release modulators which can be used in the present claims. Accordingly, the present claims do not include or require TPGS as an element of the claims. In contrast, all of the compositions taught in Amselem require TPGS and Amselem does not teach a composition which includes one of both the claimed solubilizers and the claimed release modulators. As such, Applicants

respectfully submit that the cited reference does not teach each and every element of the pending claims, and therefore it is respectfully requested that this rejection be withdrawn.

35 U.S.C. § 103 Rejections

The Examiner has rejected each of the pending claims under 35 U.S.C. § 103(a) as being allegedly unpatentable over the U.S. Patent No. 5,891,469 to Amselem et al. (hereinafter “Amselem”) patent in view of either The Merck Index (Eleventh Edition, Monograph 3924, 1989; pages 624-625) or U.S. Patent No. 3,097,144 to Banker (hereinafter “Banker”). Amselem teaches a solid dry coprecipitate of lipophilic active ingredients and which requires tocopherol polyethyleneglycol succinate (TPGS). (Col. 6, lines 23-26). The solid coprecipitate is formed when the active ingredient is co-melted with the TPGS. (Example 1) The coprecipitates can be incorporated into oral dosage forms to provide improved release of the active agent in vitro and enhanced oral bioavailability. (Col. 5, lines 49-54 and Example 1)

As the Examiner has conceded, Amselem does not teach the claimed lipophilic substances of claims 2 and 31 or the polyvinylpyrrolidone-vinyl acetate copolymer of claim 39. The Examiner has relied on The Merck Index’s teaching that fenofibrate and amiodarone are lipophilic active agents with low water solubility in order establish an alleged *prima facie* case of obviousness of claims 2 and 31. The Examiner has further relied on Banker in order to try to establish an alleged *prima facie* case of obvious for claim 39. However, Applicants assert that the presently amended claims are not obvious over the cited references and that the rejections should be withdrawn.

As discussed above, the presently pending claims have been amended to delete TPGS from the pending claims, specifically from the Markush Groups for both solubilizers and release

modulators which can be used in the present claims. Accordingly, the present claims do not include or require TPGS as an element of the claims. In contrast, the compositions taught by Amselem not only include TPGS but rely on TPGS as an “essential” component of the disclosed compositions. (Col. 6, lines 23-26).

Amselem also does not teach or suggest a composition which includes compositions having at least one of the presently claimed solubilizers and at least one of the presently claimed release modulators. Although Amselem teaches polyvinylpyrrolidone (PVP), tocopherol acetate, and other dispersion adjuvants, there is no teaching in Amselem of a composition containing a composition which requires a solubilizer of the present claims and a release modulator of the present claims. Further, as Amselem expressly teaches TPGS as an “essential” component of the disclosed compositions, one skilled in the art would be led to believe that the compositions taught by Amselem would be ineffective in enhancing the bioavailability of lipophilic agents without the inclusion of TPGS in the composition. Rather, any composition resulting from one of ordinary skill in the art following the Amselem teachings would necessarily include TPGS. As such, the teachings of Amselem effectively teach away from compositions which do not require TPGS.

As the Applicant has raised the issue of teaching away, the Applicant would like to review the current case law regarding teaching away for the Examiner’s convenience. The Court of Appeals for the Federal Circuit has clearly stated that “an applicant may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect.” In re Petersen, 315 F.3d 1325, 1331 (Fed. Cir. 2003). The Court has also stated that “[w]e have noted elsewhere, as a ‘useful general rule,’ that references that teach away cannot serve to create a prima facie case of obviousness.” (emphasis added) McGinley v.

Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001). In identifying the appropriate standard for teaching away, the Court has further stated:

“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be **discouraged from following the path set out in the reference**, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a **reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.**” (emphasis added) In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

Clearly in the present case, a person of ordinary skill in the art would be disincentivised (i.e. led away) from preparing a formulation which did not include TPGS as an essential component by following the Amselem reference.

In light of the above arguments, Applicants submit that the combination of Amselem and Merck fails to present a *prima facie* case of obviousness in that the references taken together fail to teach each and every element of the pending claims, namely a composition which includes compositions which have at least one of the presently claimed solubilizers and at least one of the presently claimed release modulators, and because one skilled in the art would be disincentivised from making the presently claimed compositions due to their failure to include TPGS.

Accordingly, it is respectfully requested that the rejection be withdrawn and the claims be allowed.

**CONCLUSION**

In view of the foregoing, the Applicants believe that Claims 1, 2, 13-15, 20-24, 29-33, and 38-39 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 23<sup>rd</sup> day of October, 2008.

Respectfully submitted,

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